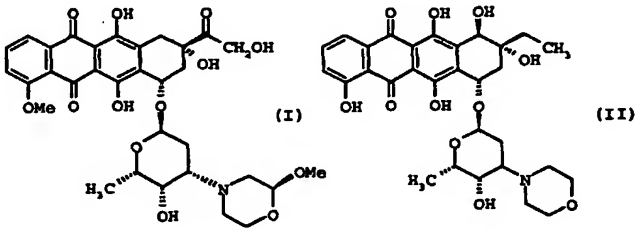
Claims

1. A combined preparation comprising a morpholinyl anthracycline derivative having formula (I), formula (II)



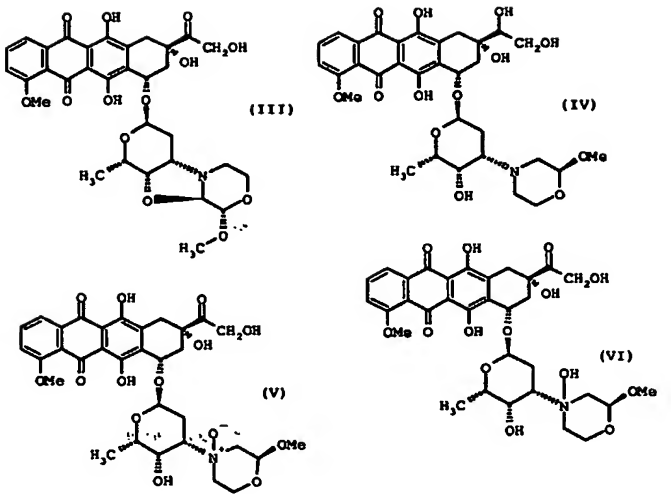
(I) (II)

a pharmaceutically acceptable salt or a pharmaceutically active metabolite thereof, administered in combination with a Cox-2 inhibitor.

2. A combined preparation according to claim 1, wherein the morpholinyl anthracycline is of formula (I).

3. A combined preparation according to claim 2, wherein the salt is the hydrochloride salt.

4. A combined preparation according to claim 1, wherein the metabolite is a metabolite of the morpholinyl anthracycline derivative of formula (I) selected from the compounds of formulae (III) to (VI)



5. A combined preparation comprising a compound of formula (III), (IV), (V) or (VI) as defined in claim 4, administered in combination with a Cox-2 inhibitor.

6. A combined preparation according to claim 1, for use in the treatment of cancer.

7. A combined preparation according to claim 1, wherein the Cox-2 inhibitor is selected from the group of chromene Cox-2 selective inhibitors consisting of compounds from B-3 to B-17 listed in Table I.

8. A combined preparation according to claim 7, wherein the morpholinyl anthracycline is of formula (I).

9. A combined preparation according to claim 8, wherein the morpholinyl anthracycline of formula (I) is in the form of its hydrochloride salt.

10. A combined preparation comprising a compound of formula (III), (IV), (V) or (VI) as defined in claim 4, administered in combination with a Cox-2 inhibitor selected from the group of chromene Cox-2 selective inhibitors consisting of compounds from B-3 to B-17 listed in Table I.

11. A combined preparation according to claim 7, wherein the chromene Cox-2 selective inhibitor is the compound B-8.

12. A combined preparation according to claim 11, wherein the morpholinyl anthracycline is of formula (I).

13. A combined preparation according to claim 12, wherein the morpholinyl anthracycline of formula (I) is in the form of its hydrochloride salt.

14. A combined preparation comprising a compound of formula (III), (IV), (V) or (VI) as defined in claim 3, administered in combination with the chromene Cox-2 selective inhibitor B-8 listed in Table I.

15. A combined preparation according to claim 1, wherein the Cox-2 inhibitor is selected from the group of tricyclic COX-2 selective inhibitors, which are celecoxib, valdecoxib, deracoxib, rofecoxib, etoricoxib, JTE-522, BMS-347070 and prodrugs thereof.

16. A combined preparation according to claim 15, wherein the tricyclic COX-2 selective inhibitors are celecoxib, rofecoxib and etoricoxib.

17. A combined preparation according to claim 15, wherein the morpholinyl anthracycline is of formula (I).

18. A combined preparation according to claim 17, wherein the morpholinyl anthracycline is of formula (I) is in the form of its hydrochloride salt.

19. A combined preparation comprising a compound of formula (III), (IV), (V) or (VI) as defined in claim 3, administered in combination with a Cox-2 inhibitor selected from the group of tricyclic COX-2 selective inhibitors which are celecoxib, valdecoxib, deracoxib, rofecoxib, etoricoxib, JTE-522, BMS-347070 and prodrugs thereof.

20. The use of a morpholinyl anthracycline derivative of formula (I), formula (II) or a pharmaceutically acceptable salt or a pharmaceutically active metabolite thereof as defined in claim 1, for the preparation of a medicament in association with a Cox-2 inhibitor for simultaneous, separate or sequential use for the treatment of cancer.

21. The use according to claim 20, wherein the morpholinyl anthracycline is of formula (I).

22. The according to claim 21, wherein the morpholinyl anthracycline of formula (I) is in the form of its hydrochloride salt.

23. The use according to claim 20, wherein the metabolite is a metabolite of the morpholinyl anthracycline derivative of formula (I) selected from the compounds of formulae (III) to (VI) as defined in claim 4.

24. The use of a compound of formula (III), (IV), (V) or (VI) as defined in claim 4, for the preparation of a medicament in association with a Cox-2 inhibitor for simultaneous, separate or sequential use for the treatment of cancer.

25. The use according to claim 20, wherein the Cox-2 inhibitor is selected from the group of chromene Cox-2 selective inhibitors consisting of compounds from B-3 to B-17 listed in Table I.

26. The use according to claim 25, wherein the morpholinyl anthracycline is of formula (I).

27. The use according to claim 26, wherein the morpholinyl anthracycline of formula (I) is in the form of its hydrochloride salt.

28. The use of a compound of formula (III), (IV), (V) or (VI) as defined in claim 4, for the preparation of a medicament in association with a Cox-2 inhibitor selected from the group of chromene Cox-2 selective inhibitors consisting of compounds from B-3 to B-17 listed in Table I for simultaneous, separate or sequential use for the treatment of cancer.

29. The use according to claim 25, wherein the chromene Cox-2 selective inhibitor is the compound B-8.

30. The use according to claim 29, wherein the morpholinyl anthracycline is of formula (I).

31. The use according to claim 30, wherein the morpholinyl anthracycline of formula (I) is in the form of its hydrochloride salt.

32. The use of a compound of formula (III), (IV), (V) or (VI) as defined in claim 4, for the preparation of a medicament in association with the chromene Cox-2 selective inhibitor B-8 listed in Table I for simultaneous, separate or sequential use for the treatment of cancer.

33. The use according to claim 20, wherein the Cox-2 inhibitor is selected from the group of tricyclic COX-2 selective inhibitors which are celecoxib, valdecoxib, deracoxib, rofecoxib, etoricoxib, JTE-522, BMS-347070 and prodrugs thereof.

34. The use according to claim 33, wherein the tricyclic COX-2 selective inhibitors is selected from celecoxib, rofecoxib and etoricoxib.

35. The use according to claim 33, wherein the morpholinyl anthracycline is of formula (I).

36. The use according to claim 35, wherein the morpholinyl anthracycline of formula (I) is in the form of its hydrochloride salt.

37. The use of a compound of formula (III), (IV), (V) or (VI) as defined in claim 4, for the preparation of a medicament in association with a Cox-2 inhibitor selected from the group of tricyclic COX-2 selective inhibitors which are celecoxib, valdecoxib, deracoxib, rofecoxib, etoricoxib, JTE-522, BMS-347070 and prodrugs thereof for simultaneous, separate or sequential use for the treatment of cancer.

38. A method for the treatment of a cancer in a subject in need of such a treatment, the method comprising administering to said subject a therapeutically effective amount of a morpholinyl anthracycline derivative of formula (I), formula (II), a pharmaceutically acceptable salt or s pharmaceutically active metabolite thereof as defined in claim 1, and a Cox-2 inhibitor, in amounts effective to produce a synergistic anticancer effect.

39. A method of claim 38, wherein the morpholinyl anthracycline is of formula (I).

40. A method of claim 39, wherein the morpholinyl anthracycline of formula (I) is in the form of its hydrochloride salt.

41. A method of claim 38, wherein the metabolite is a metabolite of the morpholinyl anthracycline derivative of formula (I) selected from the compounds of formulae (III) to (VI) as defined in claim 4.

42. A method for the treatment of a cancer in a subject in need of such a treatment, the method comprising administering to said subject a therapeutically effective amount of a compound of formula (III), (IV), (V) or (VI) as defined in claim 4 and a Cox-2 inhibitor, in amounts effective to produce a synergistic anticancer effect.

43. A therapeutic kit comprising, in suitable container means, a pharmaceutical formulation comprising a morpholinyl anthracycline derivative of formula (I), formula (II), a pharmaceutically acceptable salt or a pharmaceutically active metabolite thereof asa defined in claim 1, and a pharmaceutical formulation comprising a Cox-2 inhibitor are present within a single container means or within distinct container means.

44. A kit of claim 43, which comprises a pharmaceutical formulation of nemorubicin and a pharmaceutical formulation of Cox-2 inhibitor, within distinct container means.

45. A Kit of claim 43, for use in anticancer therapy.